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Meeting

Approaches to Dispute Resolution with CDER/CBER and the Ombudsmen's Role

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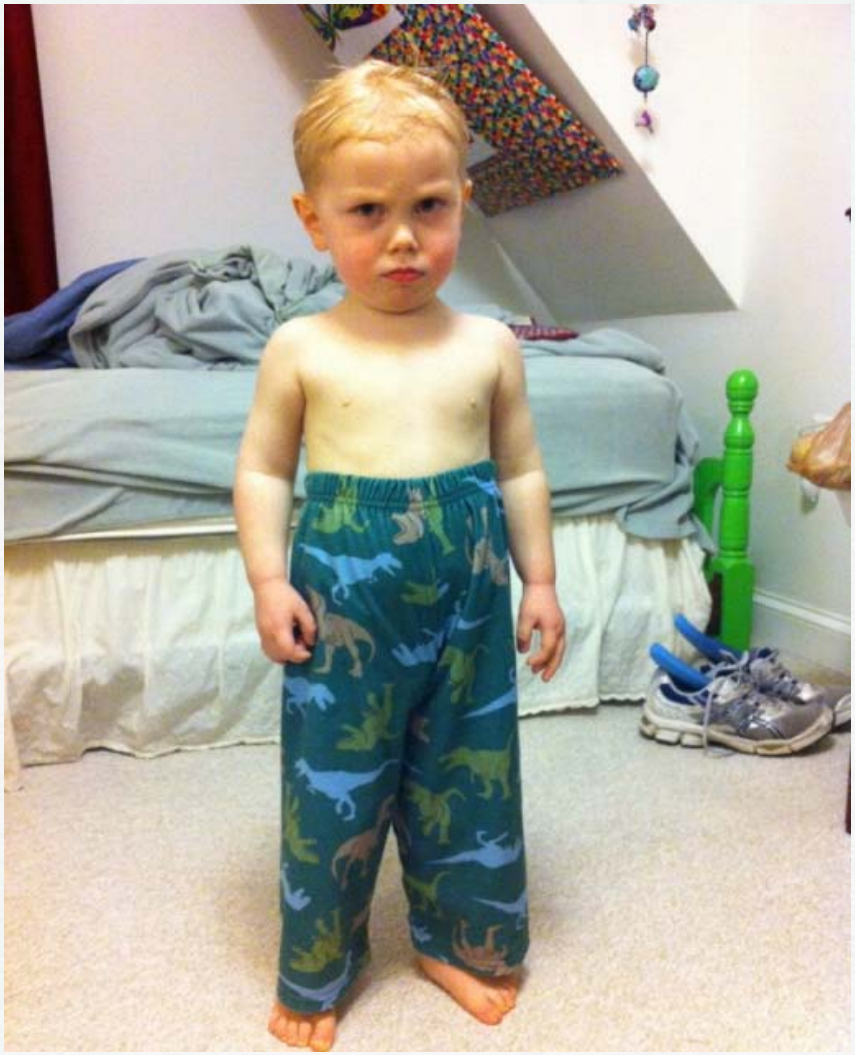

Interactions with FDA less than satisfying?

Dispute Types

- Regulatory, scientific, administrative
- Highly variable, trends change as seen in Ombudsmen's annual reports and formal dispute resolution statistics

Why they happen and prevention are not focus of the session

What Are My Options?

- Do nothing. Take what you get.
- Contact the CDER OND Enhanced Communication Team (Rachel Hartford)
- Try to work it out with the CDER/CBER team
- **Use Ombudsmen's services (informal)**
- **Invoke formal processes in Code of Federal Regulations (appeals, petitions)**
- Take legal action

FDA Ombudsmen – Who We Are

- **Food and Drug Administration, Office of Commissioner**
  - Laurie Lenkel, Andrew Moss
- **Center for Drug Evaluation and Research**
  - Virginia Behr
- **Center for Biologics Evaluation and Research**
  - Sherry Lard, Howard Balick
- **Center for Devices and Radiological Health**
  - David Buckles, Jake Romanell
- **Center for Tobacco Products**
  - Les Weinstein
- **Center for Veterinary Medicine**
  - Marcia Larkins

CDER Ombudsman's Mission

To quickly and impartially investigate complaints and resolve disputes between CDER and CDER-regulated industry, health care providers, and consumers by offering an informal, confidential, and neutral environment.

CDER Ombudsman's Vision

To improve CDER's operations and enhance transparency by providing efficient resolution of disputes and by fostering communication with stakeholders.

Who Contacts the Ombuds?

- Pharmaceutical companies
- Law firms
- Health care practitioners
- Advocacy groups
- Professional societies
- Consumers

What Do the Ombuds Do?

- Receive and investigate complaints
- Help think through options and advise
- Exercise diplomacy
- Ferret out misunderstandings
- Promote good government. Fairness, transparency, accountability
- Report systemic issues; propose solutions

Ombudsmen will NOT

- Become your personal advocate
- Violate trust of FDA employees
- Overturn a decision or action or force anyone to do so
- Work on dispute when case is pending in legal process or in formal appeals process
- Violate operating principles

Operating Principles and Ethics

- **Confidential**. If requested, holds all information confidential unless imminent harm is evident
- **Neutral & Impartial.** Remains free from bias and treat all parties without prejudice.
- **Informal**. Voluntary. No formal investigations or binding decisions or mandates.
- **Independent.** Free from outside control or influence as much as possible.

Why Use the Ombudsmen?

- Informal and efficient, saving money and time
- Improve communications and working relationships
- Deep understanding of Center operations
- Adept at interacting with FDA staff
- Unique position: high level but not management

Why Use the Ombudsmen? (2)

- Safe haven for industry, consumers, and CDER employees
  - Help industry, health care practitioners, and consumers navigate very complex FDA
  - Unbiased sounding board and advice

What Happens If I Contact the Ombuds?

- No formal submission needed
- Listen to complaint
- Ask about history
- Ask about desired outcome
- Review options
- If choose to use Ombuds
  - May request documentation or summary
  - Talk to FDA staff

To Contact or Not?

YES

- The review team is giving us mixed messages
- Can't decide best way to resolve problem
- Communications are strained or nonexistent

NO

- Ombuds should tell Division to approve my application
- Generic antipsychotic capsule colors don't match my bridal scheme
- No response on protocol (10 days old)

CDER Ombudsman Contact

Virginia L. Behr

Email: Virginia.Behr@fda.hhs.gov and CDERombudsman@fda.hhs.gov

Phone: 301 796 3436 direct

Website

- http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/CDEROmbudsman/default.htm
- Includes annual reports and FAQs

CBER Ombudsman Contact

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Phone: 301 827 0379

Website

- http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122881.htm

Formal Option: 21CFR 10.75 Appeal

- Requests supervisory review of decision
- Can be initiated by anyone
- Appeal progresses up the supervisory chain
- Under umbrella of 10.75, CDER/CBER created a process for formal dispute resolution
  - "Formal Dispute Resolution: Appeals Above the Division Level" (draft March 2013)

Formal Processes Outside Centers

- Office of Regulatory Affairs
  - Current good manufacturing practice requirements appeals, Guidance “Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP”
  - Import/customs issues
- Office of Commissioner
  - Request for Designation (reconsideration) 21 CFR Part 3
  - Petitions. 21 CFR 10.30, 10.33, and 10.35

Office of the Commissioner

- 10.30 Citizen petition
- 10.33 Request for administrative reconsideration of action
- 10.35 Request for administrative stay of action

What Factors Should I Consider?

- History of the dispute and company culture
- What attempts have you made to work it out with the decision-maker or Division?
- What exactly are you disputing?
- Was an official decision rendered?
- Information disclosure
  - FOIA-able if in administrative record
  - Proactively public (dockets)
  - Ombudsmen keep few formal records

What Factors Should I Consider? (2)

- Time and Money
  - Lawyers, loss of sales
  - Statutory/regulatory/administrative time constraints
- Product specific vs. broad issue/class issue
  - i.e., Citizen's petition are broad issue based, FDRR is product specific
- Stigma and working relationship

What Does Resolution Look Like?

Applies to both formal and informal routes

–Ask for A, B, C, get A, B, C

–Ask for A, B, C, get D and E

- Develop alternative approaches and path forward

–Not resolved – appeal again, next level up

–Denied (no merit; inadequate justification)

Key Messages

- Try to work out your issue at the source (working level)
- Unique Ombudsmen's role exists at FDA
- Take time to think through your options
- Avoid "buckshot" approach
- Be realistic about what you might achieve with the different mechanisms